

## REMARKS

Claims 1, 5-19 and 21 are pending and under examination.

### CLAIMED INVENTION IS ENABLED

Claims 1, 5-19 and 21 have been rejected under 35 USC 112, first paragraph, as allegedly not being enabled by the specification. This rejection is respectfully traversed.

The claims are directed to a method for treating a mammalian subject having a carcinoid tumor and carcinoid syndrome, comprising administering to the subject an effective amount of a replication-competent Newcastle Disease virus. The claims do not require that the NDV be oncolytic. And a virus need not be oncolytic to have anti-tumor activity.

The rejection has taken the position that “the specification, while being enabling for treating a carcinoid tumor with a replication-competent, **oncolytic** strain of Newcastle Disease Virus (NDV), does not reasonably provide enablement for any replication-competent strain of NDV.” (June 20, 2007 Office Action, page 4) (emphasis added).

The rejection assumes, without evidence, that only oncolytic strains of NDV have anti-tumor effect. The rejection is so devoted to the proposition that oncolysis is the only possible mechanism for an antitumor virus that it would deny patentability unless applicants can demonstrate “oncolysis with nonlytic strains” (June 20, 2007 Office Action, page 7), a logical impossibility as the Examiner must surely know.

The rejection goes to great effort to demonstrate that some strains of NDV are oncolytic and some are not. (June 20, 2007 Office Action, pages 4-5 “State of the art”, and page 7). That is true, but beside the point.

The issue is not whether nonlytic strains are lytic, nor is it whether all strains of NDV are oncolytic. Rather, the issue is whether the Office has met its burden of presenting adequate evidence or reasoning in support of its doubts as to the anti-tumor activity of non-oncolytic strains of NDV.

The rejection never presents any evidence or reasoning in support of its assumption that only oncolytic NDV has anti-tumor activity. To the contrary, the art recognized that non-oncolytic NDV also have anti-tumor activity. In the case of non-oncolytic NDV the anti-tumor effect is mediated through the immune system. Sinkovics, et al., in the same article cited in the rejection, states:

“Other NDV infections may assume persistent carrier culture formation (Lawton et al., 1980) in which the infected cell survives, produces complete or incomplete (noninfectious) virions, expresses viral antigens and thus attracts reactions by host antibodies and immune T cells aimed at the destruction of the infected tumor cell.” (Sinkovics, page 2, left column)

As seen from the above-quoted passage Sinkovics, et al., recognized the anti-tumor activity of replication-competent NDV generally, whether oncolytic or non-oncolytic.

The rejection identifies the La Sota strain of NDV as an example of a nonlytic strain of NDV (June 20, 2007 Office Action, page 7, line 3). But there is no reason to doubt that the La Sota strain could be useful as an antitumor therapeutic agent. Krishnamurthy, et al. report:

“We then examined four other strains of NDV (Kansas, California, La Sota, and Australian-Victoria) . . . We observed that the growth of these strains in normal and tumor cells was comparable to that of the 73-T strain. Thus, different strains of NDV are inherently tumor selective and may be equally useful as antitumor therapeutic agents.” (Krishnamurthy, et al., J. Virol. (2006) 80(11): 5145-5155 at 5148, left column) (of record).

The findings of Krishnamurthy are inconsistent with the position of the rejection that an NDV strain such as La Sota cannot have anti-tumor activity.

Applicants respectfully submit that the enablement rejection has been overcome and should be withdrawn.

## NO DOUBLE PATENTING

Claims 1, 5-8 and 16-17 have been rejected for alleged obviousness-type double patenting over claims 1-3, 6, 7, 19, 22-25 and 27 of U.S. Patent No. 7,056,689. Claims 13-15 have been provisionally rejected for alleged obviousness-type double patenting over claims 157-161, 163-170, 172, 174, 183, 196-219 and 230-232 of copending Application No. 09/958,809. Claims 1, 5-8, 13, 16 and 17 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-3, 6-8, 50, 51, 63-65, 69, 70, 73, 115-120, 132, 134, 136 and 144 of copending Application No. 10/167,652. Claims 13-15 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-6, 12, 17, 21, 22, 26-28 and 34 of copending Application No. 10/518,732, over claims 1-13 of copending Application No. 10/547,654, and over claims 1-17 over copending Application No. 10/548,057. Claims 1, 5-8 and 16-18 have been provisionally rejected for alleged obviousness-type double patenting over claims 14, 17, 18, 21, 22, 33, 34, 36-39 and 41 of copending Application No. 11/441,201.

All of the obviousness type double patenting rejections are respectfully traversed. The only reason given in support of the rejection is that the reference claims allegedly “encompass” or “overlap” with the claims of the subject application. But that is insufficient reason to sustain a *prima facie* case of nonstatutory double patenting. As stated by the CCPA, “To use the words of which the board seemed to be enamored, the broader claim ‘embraces’ or ‘encompasses’ the subject matter defined by the narrower claim. . . . This commonplace situation is not, per se, double patenting as the board seemed to think.” In re Kaplan, 789 F.2d 1574, 1577-8, 229 USPQ 678 (Fed. Cir. 1986), citing In re Sarett, 51 C.C.P.A. 1180, 327 F.2d 1005, 1014, 1015, 140 U.S.P.Q. (BNA) 474, 482, 483 (CCPA 1964).” Similarly the Board has noted that “. . . a mere genus-species or broad-narrow relationship between pending and patented claims is not a litmus test for resolving the question of double patenting of the obviousness type.” Ex parte Michno, No. 93-0877, 1993 Pat. App. LEXIS 38, \*6 (BPAI 1993).

Applicants respectfully submit that the double patenting rejections are improper and should be withdrawn.

## **CONCLUSION**

In view of the preceding remarks applicants submit that this application is now in condition for allowance. Applicants respectfully request reconsideration and withdrawal of all objections and rejections.

It is believed that no fee is required in connection with the filing of this Communication. If any fee is required, the Commissioner is hereby authorized to charge the amount of such fee to Deposit Account No. 50-1677.

Respectfully submitted,

/Lewis J. Kreisler/

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Lewis J. Kreisler  
Reg. No. 38522  
Attorney for Applicant(s)

930 Clopper Road  
Gaithersburg, MD 20878  
Phone: (240) 631-2500 x3276  
Facsimile: (240) 683-3794